



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/937,443 09/25/97 RENIRIE

A P-4782

MEDTRONIC INC
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QM12/0908

EXAMINER

EVANISKO, G

ART UNIT

PAPER NUMBER

3737

DATE MAILED:

09/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

00/937443

Applicant(s)

Examiner

Group Art Unit

3737

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/15/91.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1 - 36 is/are pending in the application.
- Of the above claim(s) 3, 4, 12, 13, 16, 17, 20, 21, 27, 29, 33 is/are withdrawn from consideration.
- ☐ Claim(s) ~~1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35~~ is/are allowed.
- ☒ Claim(s) 1, 2, 5, 11, 14, 15, 16, 19, 26, 29 - 32 is/are rejected.
- ☒ Claim(s) 22-25 34, 35 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The subject matter not described in the specification is the use of ventricular power output by itself to control the pacing means. Essential subject matter relating to the respiration sensor to determine the respiration cycle for use in the pacing means or control means is critical to the practice of the invention but is missing from the claim. As shown in figure 5 and described on page 19, the power output is sent to the rate modulator where an algorithm processes the output and sends the processed output to the rate control. But, the rate control also receives information on the respiration cycle as stated on page 19, lines 11 and 12, for "timing the change in rate...as a function of the respiration information." Also, on page 22, lines 5-7, "the system tracks patient respiration, and increases rate during inspiration relative to expiration, so as to lessen changes in ventricular cyclical power output."

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Therefore, the subject matter relating to controlling the patients heart by using only ventricular power output was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 5-11, 14, 15, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "the patient's inspiration phase" and "the patient's expiration phase" is vague and inferentially included since the respiration means has not been given a function to determine these phases.

In claim 9, "a respiratory cycle" is vague since it has been used in claim 5. Is this the same respiratory cycle?

In claim 36, the claim is incomplete for omitting essential elements, such omission amounting to a gap between the elements for not having the system contain a respiration means to adjust the pacing rate due to the respiration.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1, 2, 5, 9, 18, 19, 26, and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Ekwall (EP 0753324). Ekwall states in the first full paragraph of column 6, that the change in the stimulation energy can be achieved by increasing the number of pulses in a stimulation and to vary their number and/or amplitude and/or duration and/or timing. Since Ekwall increases the stimulation energy during inhalation, the number of pulses produced during inhalation will be increased in his system when using his method of changing the stimulation energy by varying the number of pulses. In addition, since Ekwall's system can set a maximum amplitude for the pulses at given stages in the respiratory cycle, his system will be able to limit the maximum rate of amplitude change.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekwall.

Ekwall discloses the claimed invention of delivering pacing pulses to the heart except for delivering the pacing pulses specifically to the atrium. It would have been obvious to one skilled in the art to deliver pacing pulses to the atrium to stimulate the heart, since applicant has not disclosed that delivering pacing pulses to the atrium provides any criticality and/or unexpected results and it appears that the invention would perform equally well with delivering pacing pulses to any part of the heart.

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Allowable Subject Matter

9. Claims 6-8, 10, 11, and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. Claims 22-25, 34, and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

Response to Arguments

12. Applicant's arguments filed 7/15/99 have been fully considered but they are not persuasive.

Even though Ekwall teaches that "the parameters are varied in so far as an evoked response is elicited" (page 6 of the arguments) which results in another use of his system, Ekwall still meets the broad limitations of the claims. Ekwall does teach "increasing or decreasing the pacing rate per se within the respiratory cycle" (page 6 of the arguments) since Ekwall teaches that the stimulation energy is adjusted within the respiratory cycle to be greater during inspiration

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relative to expiration. One way Ekwall teaches of increasing the energy is by increasing the number of pulses in a stimulation and to vary their number and/or amplitude and/or duration and/or timing (column 6).


Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Evanisko whose telephone number is (703) 308-2612.

GRE


September 8, 1999



William E. Kamm
Primary Examiner

